



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Robert H. Oakley et al.

Application No.: 10/633,438

Filing Date: August 1, 2003

Group Art Unit: 1646

Examiner: Unassigned

Confirmation No.: 4547

Title: Method of Screening Compositions for G Protein-Coupled Receptor Desensitization Inhibitory Activity

**FIRST
INFORMATION DISCLOSURE STATEMENT
TRANSMITTAL LETTER**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Enclosed is a **FIRST** Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

- ☒ No additional fee for submission of an IDS is required.
- ☐ The fee of \$180.00 (1806) as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- ☐ A statement under 37 C.F.R. § 1.97(e) is also enclosed.
- ☐ A statement under 37 C.F.R. § 1.97(e), and the fee of \$180.00 (1806) as set forth in 37 C.F.R. § 1.17(p) are also enclosed.
- ☐ Charge _____ to Deposit Account No. 02-4800 for the fee due.
- ☐ A check in the amount of _____ is enclosed for the fee due.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

P.O. Box 1404
Alexandria, Virginia 22313-1404
(919) 941-9240

Date: March 17, 2004

By

Joshua T. Elliott

Joshua T. Elliott

Registration No. 43,603

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope Addressed to the Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450, on March 17, 2004

Rathyn L. Boyd
(Typed or printed name of person signing the certificate)

[Signature]
(Signature of person signing certificate)

March 17, 2004
(Date of signing)



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In re Patent Application of)	
Robert H. Oakley et al.)	Group Art Unit: 1646
Application No.: 10/633,438)	Examiner: Unassigned
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for G Protein-Coupled Receptor)	
Desensitization Inhibitory Activity)	

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Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, the accompanying information is being submitted in accordance with 37 C.F.R. §§ 1.97 and 1.98.

Some of the listed documents were previously made of record in prior Application Serial No. 09/993,844, filed November 5, 2001, upon which Applicants rely for the benefits provided in 35 U.S.C. § 120. In accordance with 37 C.F.R. § 1.98, only copies of those listed documents that were not previously made of record in the prior application are enclosed. Copies of the listed U.S. patents and patent application publications are not enclosed since it is no longer required according to the July 11, 2003 waiver of the requirement for copies of cited U.S. patents and U.S. patent application publications in national patent applications filed after June 30, 2003.

The documents are being submitted within three (3) months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later. Since these documents are being filed within the time period set forth in 37 C.F.R. § 1.97(b), no fee or statement is required.

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: March 17, 2004 By: Joshua T. Elliott
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Registration No. 43,603

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Kathryn L. Boyd
(Typed or printed name of person signing the certificate)

[Signature]
(Signature of person signing certificate)

March 17, 2004
(Date of signing)

**FIRST
INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 4

Application Number 10/633,438
 Filing Date August 1, 2003
 First Named Inventor Robert H. Oakley
 Examiner Name Unassigned
 Attorney Docket Number 033072-044

U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
	20020106739	A1	Oakley et al.	08-08-2002
	20030049643	A1	Barak et al.	03-13-2003
	20040029190	A1	Barak et al.	02-12-2004
	20030013137	A1	Barak et al.	01-16-2003
	6,096,705		Lefkowitz et al.	08-01-2000
	6,110,693		Barak, et al.	08-29-2000
	6,066,476		Tsien, et al.	05-23-2000
	5,891,646		Barak, et al.	04-06-1999
	5,777,079		Tsien, et al.	07-07-1998
	5,625,048		Tsien, et al.	04-29-1997
	4,981,784		Evans, et al.	01-01-1991
	4,816,567		Cabilly, et al.	03-28-1989
	4,493,890		Morris	01-15-1985
	4,491,632		Wands, et al.	01-01-1985
	4,472,500		Milstein, et al.	09-18-1984
	4,466,917		Nussenzweig, et al.	08-21-1984
	4,451,570		Royston, et al.	05-29-1984
	4,444,887		Hoffmann	04-24-1984
	4,427,783		Newman, et al.	01-24-1984
	4,399,121		Albarella, et al.	08-16-1983
	4,342,566		Theofilopoulos, et al.	08-03-1982
	4,341,761		Ganfield, et al.	07-27-1982
	4,016,043		Schuurs, et al.	04-05-1977
	3,850,752		Schuurs, et al.	11-26-1974
	3,654,090		Schuurs, et al.	04-04-1972
	RE31,006		Schuurs, et al.	08-03-1982
	4,816,397		Boss, et al.	03-28-1989
	6,150,393		Behan, et al.	11-21-2000
	6,107,324		Behan, et al.	08-22-2000
	6,140,509		Behan, et al.	10-31-2000
	5,989,835		Dunlay, et al.	11-23-1999
	5,958,713		Thastrup, et al.	09-28-1999
	5,804,387		Cormack, et al.	09-08-1998
	5,491,084		Chalfie, et al.	02-13-1996
	5,532,157		Fink	07-02-1996
	5,482,835		King, et al.	01-09-1996
	5,468,854		McCabe, et al.	11-21-1995
	5,366,889		MacDonald, et al.	11-22-1994
	5,284,746		Sledziewski, et al.	02-08-1994

Examiner Signature

Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

Substitute for form 1449A/PTO & 1449B/PTO			Complete if Known		
FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number	10/633,438	
			Filing Date	August 1, 2003	
			First Named Inventor	Robert H. Oakley	
			Examiner Name	Unassigned	
Sheet	2	of	4	Attorney Docket Number	033072-044

U.S. PATENT DOCUMENTS				
Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
	5,576,436		McCabe, et al.	11-19-1996

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	Translation	
					Yes	No
	02/059267	A2	WO	08-01-2002		
	88/03168	A1	WO	05-05-1988		
	01/58923	A2	WO	08-16-2001		
	98/44350	A1	WO	10-08-1998		
	00/12704	A2	WO	03-09-2000		
	99/66324	A2	WO	12-23-1999		
	94/16684	A1	WO	08-04-1994		
	98/12310	A1	WO	03-26-1998		

NON-PATENT LITERATURE DOCUMENTS	
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	WALKER, Julia K. L., et al., <i>Properties of Secretin Receptor Internalization Differ from Those of the β_2-Adrenergic Receptor</i> , <u>Journal of Biological Chemistry</u> , Vol. 274, No. 44, October 29, 1999, pp. 31515-31523, The American Society for Biochemistry and Molecular Biology, Inc., U.S.A.
	Oakley et al., <i>The Cellular Distribution of Fluorescently Labeled Arrestins Provides a Robust, Sensitive, and Universal Assay for Screening G Protein-Coupled Receptors</i> , <u>ASSAY and Drug Development Technologies</u> , Vol. 1, No. 1-1, 2002, pp. 21-30.
	ANGERS, S., et al., <i>Detection of β_2-Adrenergic receptor dimerization in living cells using bioluminescence resonance energy transfer (BRET)</i> , <u>Proceedings of the National Academy of Sciences</u> , Vol. 97, No. 7, March 28, 2000, pp. 3684-3689, Proc. Natl. Acad. Sci., USA.
	ATTRAMADAL, H., et al., <i>β_2-Arrestin2, a Novel Member of the Arrestin/ β-Arrestin Gene Family</i> , <u>Journal of Biological Chemistry</u> , Vol. 257, No. 25, September 5, 1992, pp 17882-17890, The American Society for Biochemistry and Molecular Biology, Inc., USA.
	BARAK, et al., <i>Abstract #2484</i> , <u>Molecular Biology of the Cell</u> , Vol. 7, p. 427a December 1996, 6 th International Congress on Cell Biology & 36 th American Society for Cell Biology Annual Meeting, December 7 - 11, 1996, San Francisco, CA.
	BARAK, L.S., et al., <i>Constitutive arrestin-mediated desensitization of a human vasopressin receptor mutant associated with nephrogenic diabetes insipidus</i> , <u>Proceedings of the National Academy of Sciences</u> , Vol. 98, No. 1, January 2, 2001, pp. 93-98, Proc. Natl. Acad. Sci., USA.
	BARAK, L.S., et al., <i>A highly Conserved Tyrosine Residue in G Protein-Coupled Receptors is Required for Agonist-mediated β_2-Adrenergic Receptor Sequestration</i> , <u>Journal of Biological Chemistry</u> , Vol. 269, No. 4, January 28, 1994, pp. 2790-2795, The American Society for Biochemistry and Molecular Biology, Inc., USA.
	BARAK, L.S., et al., <i>A β-Arrestin/Green Fluorescent Protein Biosensor for Detecting G Protein-coupled Receptor Activation</i> , <u>Journal of Biological Chemistry</u> , Vol. 272, No. 44, October 31, 1997, pp. 27497-27500, The American Society for Biochemistry and Molecular Biology, Inc., USA.
	BARAK, L.S., et al., <i>The Conserved Seven-Transmembrane Sequence NP(X)_{2,2} Y of the G-Protein-Coupled Receptor Superfamily Regulates Multiple Properties of the β_2-Adrenergic Receptor</i> , <u>Biochemistry</u> , Vol. 34, No. 47, 1995, pp. 15407-15414.
	BARAK, L.S., et al., <i>Internal Trafficking and Surface Mobility of a Functionally Intact β_2-Adrenergic Receptor- Green Fluorescent Protein Conjugate</i> , <u>Molecular Pharmacology</u> , 51, 1997, pp. 177-184.
	BARAK, L.S., et al., <i>Real-time Visualization of the Cellular Redistribution of G Protein-coupled Receptor Kinase 2 and β-arrestin 2 during Homologous Desensitization of the Substance P Receptor</i> , <u>Journal of Biological Chemistry</u> , Vol. 274, No. 11, March 12, 1999, pp. 7565-7569, The American Society for Biochemistry and Molecular Biology, Inc., USA.
	CUBITT, A., et al., <i>Understanding, Improving and Using Green Fluorescent Proteins</i> , <u>Trends in Biochemical Sciences</u> , International Union of Biochemistry and Molecular Biology, 448-455, 1995, Elsevier Trends Journals, Oxford, UK.
	DREWS, J., <i>Drug Discovery: A Historical Perspective</i> , <u>Science</u> , Vol. 287, March 17, 2000, pp. 1960-1964, American Association for the Advancement of Science, Washington, D.C.

Examiner Signature	Date Considered
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				Examiner Name	Unassigned
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NON-PATENT LITERATURE DOCUMENTS	
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	FERGUSON, S.S.G., et al., <i>G-protein-coupled receptor regulation: role of G-protein-coupled receptor kinases and arrestins</i> , <u>Can. J. Physiol. Pharmacol.</u> , Vol. 74, 1996, pp. 1095-1110, NRC, Canada.
	FERGUSON, S.S.G., et al., <i>Molecular Mechanisms of G Protein-Coupled Receptor Desensitization and Resensitization</i> , <u>Life Sciences</u> , XP-002076355, Vol. 62, pp.1561-1565, 1998, Elsevier Publication, USA.
	FERGUSON, S.S.G., et al., <i>Role of Phosphorylation in Agonist-promoted β_2-Adrenergic Receptor Sequestration</i> , <u>Journal of Biological Chemistry</u> , Vol. 270, No. 42, October 20, 1995, pp. 24782-24789, The American Society for Biochemistry and Molecular Biology, Inc., USA.
	FERGUSON, S.S.G., et al., <i>Role of β-arrestin in Mediating Agonist-Promoted G Protein-Coupled Receptor Internalization</i> , <u>Science</u> , Vol. 271, January 19, 1996, pp363-366.
	GRADY, E., et al., <i>Mechanisms Attenuating Cellular Responses to Neuropeptides: Extracellular Degradation of Ligands and Desensitization of Receptors</i> , <u>The Journal of Investigative Dermatology Symposium Proceedings</u> , Vol. 21, No. 1, pp. 69 - 75, August 1997, The Society of Investigative Dermatology, Inc.
	HARRIS, E., et al, <i>Protein Purification Methods</i> , pp.12-18, 1989, Oxford University Press, New York, U.S.
	HAUSDORFF, W.P., et al., <i>A Mutation of the β_2-Adrenergic Receptor Impairs Agonist Activation of Adenylyl Cyclase without Affecting High Affinity Agonist Binding</i> , <u>Journal of Biological Chemistry</u> , Vol. 265, No. 3, January 25, 1990, pp. 1388-1393, The American Society for Biochemistry and Molecular Biology, Inc., USA.
	KIM, K.-M., et al., <i>Differential Regulation of the Dopamine D_2 and D_3 Receptors by G Protein-coupled Receptor Kinases and β-arrestins</i> , <u>Journal of Biological Chemistry</u> , Vol. 276 No. 40, October 5, 2001, pp. 37409-97414, The American Society for Biochemistry and Molecular Biology, Inc., USA.
	LAPORTE, S. A., et al., <i>The Interaction of β-Arrestin with the AP-2 Adaptor Is Required for the Clustering of β_2-Adrenergic Receptor into Clathrin-coated Pits</i> , <u>Journal of Biological Chemistry</u> , Vol. 275, No. 30, July 28, 2000, pp. 23120-23126, The American Society for Biochemistry and Molecular Biology, Inc., USA.
	LAPORTE, S.A., et al., <i>The β_2-Adrenergic Receptor/ β-arrestin complex recruits the clathrin adaptor AP-2 during endocytosis</i> , <u>Proceedings of the National Academy of Sciences</u> , Vol. 96, No. 7, March 30, 1999, pp. 3712-3717, Proc.Natl. Acad. Sci, USA.
	LOHSE, M., et al., <i>β-Arrestin: A Protein That Regulates β-Adrenergic Receptor Function</i> , <u>Science</u> , Vol. 248, pp. 1547-1550, June 22, 1990.
	MCCONALOGUE, K., et al., <i>Activation and Internalization of the μ-opioid Receptor by the Newly Discovered Endogenous Agonists, Endomorphin-1 and Endomorphin-2</i> , <u>Neuroscience</u> , Vol. 90, No. 3, pp. 1051-1059, 1999, Elsevier Science Ltd., Great Britain.
	MCCONALOGUE, K., et al., <i>Cellular and Subcellular Localization of G-Protein Receptor Kinases, Arrestins and G-Proteins: Implications for Receptor Regulation</i> , <u>Supplement to Gastroenterology</u> , Digestive Disease Week and the 96 th Annual Meeting of the American Gastroenterological Association, Vol. 110, No. 4, April 1996.
	MCCONALOGUE, K., et al., <i>G Protein-Coupled Receptors in Gastrointestinal Physiology II. Regulation of Neuropeptide receptors in enteric neurons</i> , <u>Receptor Regulation</u> , pp. G792-G796, 1998, American Physiological Society.
	MCCONALOGUE, K., et al., <i>Substance P-induced Trafficking of β-arrestins</i> , <u>Journal of Biological Chemistry</u> , Vol. 274, No. 23, pp.16257-16268, June 4, 1999, The American Society for Biochemistry and Molecular Biology, Inc., USA.
	MÉNARD, L., et al., <i>Members the G Protein-Coupled Receptor Kinase Family that Phosphorylate the β_2-Adrenergic Receptor Facilitate Sequestration</i> , <u>Biochemistry</u> , Vol. 35, No. 13, 1996, pp. 4155-4160, The American Chemical Society.
	MÉNARD, L., et al., <i>Synergistic Regulation of β_2-Adrenergic Receptor Sequestration: Intracellular Complement of β_2-Adrenergic Receptor Kinase and β_2-Arrestin Determine Kinetics of Internalization</i> , <u>Molecular Pharmacology</u> , Vol. 51, No. 5, May 1997, pp. 800-808, The American Society for Pharmacology and Experimental Therapeutics.
	MHAOUTY-KODJA, S., et al., <i>Constitutively Active Alpha-1b Adrenergic Receptor Mutants Display Different Phosphorylation and Internalization Features</i> , <u>Molecular Pharmacology</u> , Vol. 55, No. 2, February 1999, pp. 339-347, The American Society for Pharmacology and Experimental Therapeutics.
	ORMÖ, M., et al., <i>Crystal Structure of the Aequorea victoria Green Fluorescent Proteins</i> , <u>Science</u> , Vol. 273, pp. 1392-1395, 1996, American Association for the Advancement of Science, Washington D.C.
	OAKLEY, R.H., et al., <i>Association of β-Arrestin with G Protein-coupled Receptors during Clathrin-mediated Endocytosis Dictates the Profile of Receptor Resensitization</i> , <u>Journal of Biological Chemistry</u> , Vol. 274, No. 45, November 5, 1999, pages 17201-17210, The American Society for Biochemistry and Molecular Biology, Inc., USA.

Examiner Signature	Date Considered
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	OAKLEY, R.H., et al., <i>Differential Affinities of Visual Arrestin, β-Arrestin1, and β-Arrestin2 for G Protein-coupled Receptors Delineate Two Major Classes of Receptors</i> , <u>Journal of Biological Chemistry</u> , Vol. 275, No. 22, June 2, 2000, pp. 17201-17210, The American Society for Biochemistry and Molecular Biology, Inc., USA.
	OAKLEY, R.H., et al., <i>Molecular Determinants Underlying the Formation of Stable Intracellular G Protein-coupled Receptor – β-Arrestin Complexes after Receptor Endocytosis</i> , <u>Journal of Biological Chemistry</u> , Vol. 276, No. 22, June 1, 2001, pp. 19452 - 19460, The American Society for Biochemistry and Molecular Biology, Inc., USA.
	YOKOE, <i>Spatial Dynamics of GFP-tagged proteins investigated by local fluorescence enhancement</i> , <u>Nature Biotechnology</u> , Vol. 14, pp. 1252 - 1256, October 14, 1996.
	ZHANG, J., et al., <i>Cellular Trafficking of G Protein-coupled Receptor/ β-Arrestin Endocytic Complexes</i> , <u>Journal of Biological Chemistry</u> , Vol. 274, No. 16, April 16, 1999, pp. 10999-11006, The American Society for Biochemistry and Molecular Biology, Inc., USA.
	ZHANG, J., et al., <i>A Central Role for β-Arrestins and Clathrin-coated Vesicle-mediated Endocytosis in β_2-Adrenergic Receptor Resensitization</i> , <u>Journal of Biological Chemistry</u> , Vol. 272, No. 43, October 24, 1997, pp. 27005-27014, The American Society for Biochemistry and Molecular Biology, Inc., USA.

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